REMARKS

This application is amended in a manner to place it in condition for allowance.

Status of the Claims

Claims 45-50 are new.

New claim 45 is an independent claim directed to the subject matter of claim 23 (the branching enzyme is extracted from unicellular algae), which was not rejected by prior art, combined with the subject matter of independent claim 19 and 20, respectively, and, alternatively, that the branching enzyme is extracted from *E. coli*, as demonstrated in Example 4 of the specification.

New claim 46 further limits these features.

New dependent claims 47 and 49 correspond to dependent claim 21.

New dependent claims 48 and 50 correspond to the features of claim 24.

Claims 19-24 and 31-50 remain pending.

Claim Rejections-35 USC §112, 2nd paragraph

Claims 31-37 and 39-44 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite. This rejection is respectfully traversed for the reasons below.

The position of the Official Action was that claims 31, 34, 39, and 42 first recite a broad limitation of between 2.5 and 10% of alpha-1,6 glucosidic bonds and then follow by a narrower statement of the range/limitation: "wherein said soluble branched polymers of glucose in isolated and purified form comprise, at every 10 to 14 glucose units, an additional chain of glucose units".

The Official Action stated that the narrow range of one side chain every 10 to 14 glucose units would, as the branching enzyme introduces side chains as alpha-1,6 bonds, indicate that the branched starch contains between about 6.7 and 9.1% alpha-1,6 glucosidic bonds, which would be significantly narrower than the broad limitation recited in said claims.

The Official Action further objected to dependent claims 32, 36, and 37 which include additional limitations.

However, it is not clear how the branching rate from 6.7 to 9.1% was determined from the recitation that the polymer comprises 10 to 14 glucose residues, an additional chain of glucose units.

The polymer is not connected to a long succession of glucose units linked by alpha 1,4. Rather, the polymer exists naturally as alpha 1,6, branching points and not necessarily every 10 to 14 residues.

That is, it is the branching enzyme that causes branching at a residue 10 to 14 units of glucose after an

existing branching point. Before 10 units of glucose, branching is not possible because of steric hindrance. After 14 units, it exceeds the capacity of connecting of its active site. Thus, as soon as the branching enzyme can, a connection is made every 10 to 14 glucose residues.

Thus, the percentage of alpha-1,6 glucosidic bonds and the location of an additional chain every 10 to 14 glucose units are appropriately recited in the same claim without rendering the claim indefinite.

Therefore, withdrawal of the indefinite rejection is respectfully requested.

Claim Rejections-35 USC §112, 1st paragraph

a) New Matter

Claims 19-24 and 31-44 were rejected under 35 U.S.C. §112, first paragraph, for not complying with the written description requirement. This rejection is respectfully traversed for the reasons below.

The position of the Official Action was that soluble branched polymers of glucose in isolated and purified form comprising at every 10 to 14 glucose units an additional chain of glucose units were new matter as they were not described in the specification.

The specification provides the use of purified branching enzyme.

One of ordinary skill in the art understands that the effect of a branching enzyme, e.g., as described by Wikipedia (http://en.wikipedia.org/wiki/Branching_enzyme), is as follows:

"… *Every 10 to 14 glucose units a side branch with an additional chain of glucose units occurs. The side chain attaches at carbon atom 6 of a glucose unit, and the linkage is termed an alpha-1,6 glycosidic bond. To form this connection a separate enzyme known as a branching enzyme is used. A branching enzyme attaches a string of seven glucose units to the sixth carbon of a glucose unit, usually in an interior location of the glycogen molecule.*"

Therefore, the reference to the use of a branching enzyme in a claim implicitly includes the above technical features, and withdrawal of the new matter rejection is respectfully requested.

b) Enablement

Claims 19-24 and 31-44 were rejected under 35 U.S.C. §112, first paragraph, for not complying with the enablement requirement. This rejection is respectfully traversed for the reasons below.

The Official Action asserted that the specification, while being enabling for a method involving certain specific branching enzymes, for example from *E. coli*, *C. reinhardtii*, or maize, the specification does not reasonably provide enablement for a method utilizing any possible starch branching enzyme whatsoever expressed in any genetically modified expression system whatsoever. The Official Action concluded that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Official Action referred to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) in support of this conclusion.

However, applicant respectfully submits that this rejection appears to be based on a misunderstanding of *branching enzyme*, as disclosed and as generally understood by one of ordinary skill in the art.

A branching enzyme is a conventional chemical reagent, of course less usual than water or ethanol, but anyway conventional as explained, for example, in Wikipedia as discussed above.

Reference to *In re Wands* implies that the present invention were directed to completely new enzymes with a new activity and to their process of preparation. However, this is not true in the instant case.

The present invention is directed to a novel process for making soluble branched polymers of glucose containing essentially no beta-glucosidic bonds, from a starting product which is starch or a starch derivative. As is known, starch is a polysaccharide carbohydrate forming a chain consisting of a large number of glucose monosaccharide units joined together by glycosidic bonds.

In the claimed invention, the branching enzyme is a conventional chemical reagent, here a kind of catalyst, and is one of the claimed technical means which achieves the claimed results. The enzyme is functionally defined like any catalyst, for example.

The objection raised against the terms "purified branching enzyme" and "the branching enzyme is selected from the group consisting of glycogen branching enzymes, starch branching enzymes" that they are too broad since some of them rely on yet unavailable entities is not accurate. As previously argued in the amendment of April 10, 2009, the specification clearly discloses selecting conventional branching enzymes to produce a specific product, “wherein the branched polymers of glucose comprise, at every 10 to 14 glucose units, an additional chain of glucose units” as claimed. Accordingly, any purified branching enzyme known to have this effect (i.e., any EC 2.4.1.18 enzyme) may be used in the claimed process.

The Official Action alleged that branching enzymes differ from chemical reagents such as hydrochloric acid in that the term refers to a broad range of different compounds having a certain effect, while a chemical term such as hydrochloric acid refers to a single chemical entity that is identical no matter what its source.

However, this comparison is inappropriate.

It would be more appropriate to compare "branching enzymes" to compounds such as "hydrogenation catalysts" which are defined by their function and facilitate a reaction like branching enzymes. Various hydrogenation catalysts are available but all allow hydrogenation.

Hydrogenation catalysts bind both the H_2 and the unsaturated substrate and facilitate their union. Platinum group metals, particularly platinum, palladium, rhodium, and ruthenium, form highly active catalysts, which operate at lower temperatures and lower pressures of H_2. Non-precious metal catalysts, especially those based on nickel (such as Raney nickel and Urushibara nickel) have also been developed as economical alternatives, but they are often slower or require higher temperatures. Two broad families of catalysts are known – homogeneous catalysts and heterogeneous catalysts. Homogeneous catalysts dissolve in the solvent that contains the unsaturated substrate. Heterogeneous catalysts are solids that are suspended

in the same solvent with the substrate or are treated with gaseous substrate.

The Official Action also alleged that by applicant's own admission, "branching enzyme" refers not to a particular structure or sequence but to a technical effect and by merely reciting the technical effect of the enzyme rather than a particular sequence, source, or structure, Applicant has failed to limit the scope of the claims to enzymes that would in fact be accessible to one skilled in the art.

However, applicant explained that a branching enzyme is to be compared for example to a hydrogenation catalyst and not to HCl or to unknown compounds.

Therefore, in view of the above, the claims comply with the enablement requirement, and withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §103

Claims 19-22 and 31-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over OKADA et al. U.S. 4,454,161 (OKADA) in view of SENKELESKI et al. U.S. 5,562,937 (SENKELESKI) in view of SANDSTROM et al. WO95/22562 (SANDSTROM), also published as BYRNOLF et al. U.S. 5,929,052 (BYRNOLF). This rejection is respectfully traversed for the reasons below.

Process Claims

The Official Action remarked that the applicant argued that SENKELESKI includes a hydrolysis step that is incompatible with the claimed invention, and the Official Action asserted that SENKELESKI was only relied upon for its teaching of high-pressure steam cooking gelatinization, not for the teaching of enzymatic hydrolysis. However, applicant respectfully submits that applicant's argument was appears to have been misunderstood.

The primary reference is OKADA, which teaches a branched alpha-glucose polymer (starch) produced by the activity of a branching enzyme, for example an animal, plant, or microorganism branching enzyme in a starch such as amylopectin. A gelatinized solution of the starch is subjected to the action of the branching enzyme and then used, after concentration and/or drying, in food products. A bacillus branching enzyme is reported having an optimal temperature of about 25°C and being stable up to about 45°C. These starches display a reduced propensity for retrogradation.

The Official Action acknowledged that OKADA does not disclose a method in which the starch is gelatinized by a treatment at over 130°C and 3.5 bars, as recited in the instant claims. OKADA also does not explicitly disclose a method in which the amount of branching enzyme is between 50-2000 units and the reaction is carried out at exactly 30°C. OKADA further does not disclose a composition having a branch point at every

10-14 glucose units, or one having the molecular weight, percent of alpha 1,6 bonds, or reducing sugar content recited in the instant claims.

However, the Official Action concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of OKADA in view of the ancillary reference SENKELESKI to produce a branched product as described by SANDSTROM, having the same molecular weight and degree of branching but lacking beta-glycosidic bonds. According to the Official Action, one of ordinary skill in the art would have recognized that the enzymatic treatment of OKADA in view of SENKELESKI produces the same result, namely increased branching, as the acid treatment of SANDSTROM, and that the two treatments are therefore interchangeable.

Applicant respectfully disagrees with this conclusion. Considering 35 U.S.C. §103(a), the question is whether there is in SENKELESKI some teaching, suggestion, or motivation to modify the teachings of OKADA, by combining the teaching of high-pressure steam cooking treatment of SENKELESKI with the enzymatic process of OKADA in order to arrive at the claimed invention.

However, the cited documents themselves provide no apparent reason for one of ordinary skill in the art to combine OKADA and SENKELESKI.

OKADA teaches a branched alpha-glucose polymer (starch) produced by the activity of a branching enzyme.

SENKELESKI discloses a method wherein [the gelatinized starch is enzymatically hydrolyzed] *with beta-amylase or glucoamylase until up to about 60% by weight of the starch has been degraded to maltose or glucose* " (Summary and claims 1 and 7) which respectively a monosaccharide and a disaccharide. The starch, in order to be processed in this manner, is first steam cooked at a temperature of 120°C to 170°C at a pressure of 60-80 psi, which is equivalent to about 4.1-5.5 bar.

Therefore SENKELESKI, seeks to cut the main chain of the starting product into short pieces: monosaccharides or disaccharides. That is, an important objective of SENKELESKI is to decrease the size and weight of the treated molecule.

This objective is contrary to the present invention, and OKADA. In the present invention, not only is the main chain of glucose monosaccharide units joined together by 1,4 linkages maintained, but additional chains are laterally branched onto this main chain. Thus, there is an increase of size and weight of the molecule, which is the opposite effect required by SENKELESKI.

For the above reasons, as SENKELESKI seeks to cut the main chain of the starting product, SENKELESKI would teach away from both OKADA and the presently claimed process aiming at an

increase of size and weight of the starting molecule. One skilled in the art would never have combined the treatment of SENKELESKI with the process of OKADA.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). That is, the fact that SENKELESKI teaches high-pressure steam cooking gelatinization is not sufficient to establish that one skilled in the art would have been motivated to even approach the claimed invention which sets out add chains to the starch molecule.

Moreover, it is indeed a key condition for assessing obviousness that the prior art must be considered as a whole and without the knowledge of the solution provided in the patent application in order to avoid hindsight analysis.

In the present case, one skilled in the art had no reason to consider SENKELESKI since its only link to the claimed invention is the similarity with one of the features of the combination of features described in the application, i.e. the solution of the problem.

Accordingly, the combination of OKADA and SENKELESKI is the result of hindsight analysis.

Regardless of the ability of SANDSTROM to teach that for which it was offered, SANDSTROM is unable to remedy the deficiency of the proposed combination for reference purposes.

Product Claims

The Official Action alleged that the branched starch (alpha-glucose polymer) of SANDSTROM possess the same structural characteristics (size, degree of branching) as those described in the instant specification.

The Official Action acknowledged that the starches of SANDSTROM differ from the claimed invention in that they possess beta-glucosidic linkages.

However, the Official Action concluded that the presence of beta-glucosidic bonds in the compounds of SANDSTROM is an incidental result of the particular acid treatment used, and is not seen to be necessary for the desired properties, namely stability and reduced osmolality, present in the starches of SANDSTROM.

However, this appears to be pure speculation, and there is no finding of fact to support this conclusion.

Moreover, the conclusion that it would have been obvious to one of ordinary skill in the art to optimize the various characteristics of the starch of SANDSTROM, such as degree of branching and molecular weight, to arrive at the

values disclosed in instant claims 32, 36, and 37, appears to be unreasonable.

This conclusion is based on the combination of OKADA, SENKELESKI, SANDSTROM and further optimization. Indeed, for the reasons discussed above relative to the process claims the combination OKADA and SENKELESKI is itself unreasonable, e.g., SENKELESKI would lead to decrease molecular weight.

Therefore the claimed invention taken as a whole is unobvious over the cited prior art, and withdrawal of the rejection is respectfully requested.

New claims 45-50 are also believed to be unobvious over the cited prior art as they include the subject matter of claims 23 and 24 which were not rejected by prior art.

Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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